

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on August 16, 2007. A Request for Continued Examination ("RCE") is submitted herewith. The Director is authorized to charge the amount of \$810.00 for the cost of the RCE and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-434 on the account statement.

Claims 1-30 are pending in this application. Claims 11-24 were previously withdrawn. In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. §112, second paragraph. Claims 1-10 and 25-30 are rejected under 35 U.S.C. §103. Claims 1-10 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting. In response, Claims 1 and 4 have been amended. These amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office asserts that Claim 1 is vague and indefinite in that it is unclear whether the percentage by weight recited pertains to each of the at least one probiotic lactic acid bacterium and at least one carotenoid or to both together. See, Office Action, page 2, lines 16-18. Additionally, the Patent Office asserts that the phrase "at least one carotenoid or derivative is not particularly defined in the specification. *Id.* at lines 19-22.

In response, Applicants have amended Claim 1 to recite, in part, an orally administrable composition for the photoprotection of the skin comprising at least one carotenoid, wherein the carotenoid is present in the composition in an amount from $10^{-12}\%$ to 20% by weight. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 15, lines 21-27. Therefore, Applicants have deleted the term "derivative" and have specified that it is the at least one carotenoid that is present in the composition in an amount

from $10^{-12}\%$ to 20% by weight and respectfully submit that one of ordinary skill in the art would understand the scope of the presently claimed subject matter.

Claim 4 is also rejected under 35 U.S.C. §112, second paragraph as being confusing for lacking antecedent basis in Claim 3 because there are several *Lactobacillus* and *Bifidobacterium* strains belonging to various species and it cannot readily be ascertained which of the deposited strains belongs to which species. See, Office Action, page 2, lines 26-30. In response, Claim 4 has been amended to identify the lactic acid bacteria strains of *lactobacilli* and *bifidobacteria* identified by each respective deposit number. The amendment does not add new matter. This amendment is supported in the specification at, for example, page 15, lines 1-6. Based on at least these noted reasons, Applicants believe that Claims 1-10 and 25-30 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1-10 and 25-30 under 35 U.S.C. §112, second paragraph be reconsidered and the rejections be withdrawn.

In the Office Action, Claims 1-10 and 25-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. European Patent No. 1020123 to Vesely et al. ("*Vesely*") taken with U.S. Patent No. 6,156,355 to Shields, Jr. et al. ("*Shields*"), U.S. Patent No. 7,037,708 to Runge et al. ("*Runge*"), WO/00/070972 to Berggren et al. ("*Berggren*"), U.S. Patent No. 5,603,930 to Brassart et al. ("*Brassart*"), and further taken with U.S. Patent No. 4,806,368 to Reddy ("*Reddy*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Currently amended independent Claim 1 recites, in part, an orally administrable composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid or derivative, present in the composition in an amount from $10^{-12}\%$ to 20% by weight, included in an orally acceptable carrier, the composition further comprising a yeast extract. The presently claimed oral composition includes an admixture of very specific constituents that surprisingly and unexpectedly elicit an enhanced effect or response in respect of the photoprotection of the skin. See, Specification, page 14, lines 6-11. Applicants respectfully submit that the cited references are deficient with respect to the presently claimed subject matter.

Applicants respectfully disagree with the Patent Office's assertion that "it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.* and Berggren *et al.* by providing a composition comprising a photoprotective amount of probiotic strains CNCM I-1225 and CNCM I-1226 as suggested by the teachings of Brassart *et al.* for the expected benefit of providing a healthful composition comprising a probiotic strain known to have favorable effects against disease and carotenoids such as β -carotene know[n] to have at least antioxidant[] effects." See, Office Action, page 6, lines 6-12. Instead, Applicants respectfully submit that the skilled artisan would have no reason to combine the cited references to obtain the present claims because the cited references are directed to unrelated products that have completely different objectives and fail to even recognize the surprising and unexpected effect that the specific composition has on the photoprotection of the skin.

For example, *Vesely* is directed toward a beverage containing live bacteria that is used to increase, balance and supplement intestinal flora. See, *Vesely*, col. 3, [0016]. *Shields* is entirely directed toward canine food formulations that optimize digestibility of nutrients in specific canine breeds. See, *Shields*, column 3, lines 30-36. *Runge* is entirely directed toward dry microorganism cultures and the processes for producing same. See, *Runge*, Abstract. *Berggren* is entirely directed toward a sports drink that is designed to increase the energy and fluid levels in an individual, as well as reduce stress. See, *Berggren*, page 2, line 39-page 3, line 4. *Brassart* is entirely directed toward a biologically pure culture of a lactic acid bacterium strain. See, *Brassart*, Summary of the Invention. *Reddy* is entirely directed toward a supplement that permits the longevity of certain health promoting bacteria in tablets. See, *Reddy*, column 1, lines 10-20. As such, Applicants respectfully submit that there is absolutely no guidance in the cited reference for one of skill in the art to choose the active agents and amount of agents present in the instant claims to achieve the unexpectedly improved photoprotective effect on the skin as Applicants have done.

Moreover, in contrast to the presently claimed subject matter, the cited references are completely unconcerned with blocking or reducing the adverse clinical, histological and immunological effects of solar radiation exposure on the skin, as demonstrated above.

Consequently, the skilled artisan would have no reason to combine the cited references to arrive at a photoprotecting composition in accordance with the present claims, nor would the skilled artisan have any reasonable expectation of success in combining the cited references. Moreover, the number of references (6) relied on by the Patent Office to support the present rejection provides evidence by itself that the present claims are not obvious. For at least the reasons discussed above, Applicants respectfully submit that Claims 1-10 and 25-30 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejections of Claims 1-10 and 25-30 under 35 U.S.C. §103 be withdrawn.

In the Office Action, Claims 1-10 and 25-30 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claim 9 of copending, commonly owned Application No. 10/505,285, Claims 1-13 and 22-32 of copending, commonly owned Application No. 10/504,906, and Claims 1-19 of of copending, commonly owned Application No. 11/159,198. For purposes of advancing the prosecution of this application, Applicants previously elected to overcome such rejections through a Terminal Disclaimer. Such election shall not be deemed an admission as to the propriety or accuracy of the Office Action's conclusions or rejections. Applicants respectfully request that the previously submitted terminal disclaimer be entered by the Patent Office.

Accordingly, Applicants respectfully request that the provisional double patenting rejections of Claims 1-10 and 25-30 under obviousness-type double patenting be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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